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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,510	11/08/2001	Charles S. Schasteen	NVI 5183.1	9657

321 7590 11/18/2003

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,510	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-143 is/are pending in the application.
- 4a) Of the above claim(s) 31-112 and 120-135 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30, 113-119 and 136-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,5,6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-30, 113-119 and 136-143 with traverse is acknowledged. In view of Applicant's amendment and remarks, the species election as set forth in the Election Restriction mailed March 26, 2003 is withdrawn. Claims 1-30, 113-119 and 136-143 are under examination and consideration. Claims 31-112 and 120-135 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The specification is objected because of the use of embedded hyperlink and/or other form of browser-executable code on pages 41 and 42. The hyperlinks can be readily changed and therefore, may not be available to the public. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. Claim 19 objected to because of the following informalities: Claim 19 should have a "." inserted after 7.8. Appropriate correction is required.

Drawings

4. The drawings are objected to by the Draftsman under 37 CFR 1.84 or 1.152. See the attached form PTO 948.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 6 and 136 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 136 are indefinite because it recite "substantially free". It is unclear as to what the Applicant is referring? "substantially exclusive lacks definitiveness." *Quaker Oil Corp. v. Quaker State Oil Refining Corp.* (PO TM TappBd) 161 USPQ 547.
6. Claim 113-119 and 136-143 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 116, 118 and 141 in particular are indefinite because it recite "characterized as". It is unclear as to what the Applicant is referring?
7. Claims 136-143, in particular claim 139 recite the limitation "wherein said vaccine". There is insufficient antecedent basis for "vaccine" in the claim. The claims are drawn to a composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-15, 19-23, 113-119 and 136-142 are rejected under 35 U.S.C. 102(b) as anticipated by Murray et al (*United States Patent No: 4,639, 372, published January 27, 1987*).

Claims 1-15, 19-23, 113-119 and 136-142 are drawn to a composition for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate.

Murray et al teach coccidiosis vaccines that are prepared by disrupting feces and intestinal contents of *Eimeria* in a blender. Murray et al teach the oocysts were isolated by flotation of the oocysts on a 20% saline solution and treated with 5.25% sodium hypochlorite and washed in PBS (columns 2-4). Claim limitations such as “the composition ameliorates a decline or decrease in post-challenge performance” and “a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations” are being viewed as a limitation of intended use.

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The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart

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patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition*. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. Conkle et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the

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applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-15, 19-23, 113-119 and 136-143 are rejected under 35 U.S.C. 103(a) as unpatentable over Murray et al (*United States Patent No: 4,639, 372, published January 27, 1987*) in view of Brown et al (*U.S. Patent No. 6, 019, 985, published February 1, 2000*).

Claims 1-15, 19-23, 113-119 and 136-143 are drawn to a composition for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate further comprising *Propionibacterium acnes*.

Murray et al teach coccidiosis vaccines that are prepared by disrupting feces and intestinal contents of *Eimeria* in a blender. Murray et al teach the oocysts were isolated by flotation of the oocysts on a 20% saline solution and treated with 5.25% sodium hypochlorite and washed in PBS (columns 2-4). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use.

Murray et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as "the composition ameliorates a decline in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the coccidiosis vaccines comprising oocysts of Murray et al because Brown et al teach

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compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.


Status of the Claims

10. No claims allowed.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is 703-308-4735. The examiner can normally be reached on M-F 9:30pm-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


MARK NAVARRO
PRIMARY EXAMINER


Vanessa L. Ford

Biotechnology Patent Examiner

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November 4, 2003